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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,297	02/17/2004	Apollon Papadimitriou	20619US1	9601

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/780,297

Applicant(s)

PAPADIMITRIOU, APOLLON

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18, 22-37 and 39-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18, 22-37 and 39-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/853,731.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/13/05; 4/11/05; 5/6/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Status of the Claims

1. Claims 1-16, 18, 22-37 and 39-68 are pending.

Applicants' amendment and declaration of Appollin Papadimitriou filed on March 16, 2005 are acknowledged. Applicants' response has been fully considered. Claims 1, 3, 4, 9, 13-15, 22, 24, 25, 30, 35, 41-44, 49, 51 and 53-58 have been amended, claims 17, 19-21 and 38 have been cancelled, and new claims 60-68 have been added. Thus, claims 1-16, 18, 22-37 and 39-68 are examined.

Objection Withdrawn

2. The previous objection to Fig. 10 is withdrawn in view of applicant's submission of a substituted Fig. 10 in the amendment filed March 16, 2005.
3. The previous objection to claims 14, 17, 35 and 38 is withdrawn in view of applicant's amendment to the claims, applicants' cancellation of the claim, and applicant's response at page 18 of the amendment filed March 16, 2005.

Rejection Withdrawn

Claim Rejections-Obviousness Type Double Patenting

4. The previous rejection of claims 17, 19-21 and 38 as being provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/853,731, is withdrawn in view of applicant's cancellation of the claims in the amendment filed March 16, 2005.

Claim Rejections - 35 USC § 112

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5. The previous rejection of claims 4, 9, 25, 30 and 58 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in view of applicant's amendment to the claims, and applicant's response at page 20 of the amendment filed March 16, 2005.

Claim Rejections - 35 USC § 102

6. The previous rejection of claims 1-4, 6-9 and 11 under 35 U.S.C. 102(b) as being anticipated by Yamazaki *et al.* (EP 0909564), is withdrawn in view of applicant's amendment to the claims, and applicant's response at pages 20-22 of the amendment filed March 16, 2005.

7. The previous rejection of claims 1-4, 6, 7, 9-11, 22-25, 27, 28, 30-32 and 46 under 35 U.S.C. 102(b) as being anticipated by Woog *et al.* (U. S. Patent 4,992,419), is withdrawn in view of applicant's amendment to the claims, and applicant's response at pages 22-23 of the amendment filed March 16, 2005.

8. The previous rejection of claims 1-18, 22-39, 43, 46, 48-53, 55 and 59 under 35 U.S.C. 102(e) as being anticipated by Bailon (U.S. Patent No. 6,583,272), is withdrawn in view of applicant's amendment to the claims, applicant's cancellation of the claim, declaration of Appollin Papadimitriou, and applicant's response at pages 23-24 of the amendment filed March 16, 2005.

Claim Rejections - 35 USC § 103

9. The previous rejection of claims 1-4, 6-9 and 11-16 under 35 U.S.C. 103(a) as being unpatentable over Yamazaki *et al.* (EP 0909564) in view of Rosen *et al.* (WO 92/06116) and Elliot *et al.* (EP 0640619), is withdrawn in view of applicant's amendment to the claims, and applicant's response at pages 24-25 of the amendment filed March 16, 2005.

Claim Objections

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10. Claim 47 is objected to because of the use of the term "said solution further containing 10 mM methionine". Since the solution already contains methionine, the word "further" should not be used. Appropriate correction is required.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1, 18, 22, 39 and 49-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/014,363. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 18, 22, 39 and 49-58 in the instant application disclose a liquid pharmaceutical composition comprising an EPO glycoprotein product having the in vivo biological activity, a multiple charged inorganic anion, a buffer and methionine, wherein the glycoprotein product can be a pegylated EPO such as EPO being linked to $-\text{CO}-(\text{CH}_2)_x-(\text{OCH}_2\text{CH}_2)_m-\text{OR}$. This is an obvious variation in view of claims 1-16 in the copending application which disclose a conjugate comprising an EPO glycoprotein linked to $-\text{CO}-(\text{CH}_2)_x-(\text{OCH}_2\text{CH}_2)_m-\text{OR}$, and a pharmaceutical composition comprising the conjugate. Although the claims of the copending application are directed to a conjugate of EPO with

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poly(ethyleneglycol) and a pharmaceutical composition comprising the conjugate, where the components in the composition are not specified, the specification does indicate the composition of the invention comprises the components such as sodium phosphate, sodium sulfate, mannitol, methionine and pluronic F68 in the most preferred embodiment (paragraph [0121]). Thus, claims 1, 18, 22, 39 and 49-58 in present application and claims 1-16 in the copending application are obvious variations of a pharmaceutical composition comprising a conjugate of EPO with poly(ethyleneglycol), a multiple charged inorganic anion, a buffer and methionine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response, applicants request this provisional rejection be held in abeyance until there is indication of allowable subject matter in either application; and applicants also indicate the claims of the instant application are directed to a specific pharmaceutical formulation containing an EPO glycoprotein, while the claims of co-pending application (should be 10/014,363, not 10/104,363 as indicated at page 19 of the response) are directed to a particular EPO glycoprotein product in whatever form, not just in a pharmaceutical formulation. These different types of claims, compound versus formulation claims are not properly subject to obvious double patenting rejection.

The response has been fully considered. However, the argument is not found persuasive because the claims of copending application are directed to a particular EPO glycoprotein product and a pharmaceutical formulation, and the specification indicates in the most preferred embodiment, the composition of the invention comprises the EPO product, sodium phosphate, sodium sulfate, mannitol, methionine and pluronic F68 (paragraph [0121]). Thus, it is obvious

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that the particular EPO product can be used for preparing a pharmaceutical formulation comprising the EPO and other ingredients such as phosphate, sulfate, mannitol and methionine for therapeutic use. Regarding the provisional rejection being held in abeyance, the allowable subject matter cannot be indicated as long as the rejection remains.

12. Claims 1-16, 18, 22-37 and 39-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-35, 38-42, 51-55, 59-61 and 67-77 of copending Application No. 09/853,731. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-16, 18, 22-37 and 39-68 in the instant application disclose a liquid pharmaceutical composition consisting essentially of an EPO glycoprotein product having the in vivo biological activity, a multiple charged inorganic anion, a buffer at pH of 5.5 to 7.0 and methionine, where the EPO product can be a pegylated EPO product. This is an obvious variation in view of claims 23-35, 38-42, 51-55, 59-61 and 67-77 in the copending application which disclose a liquid pharmaceutical composition comprising a pegylated EPO glycoprotein product having the in vivo biological activity, a multiple charged inorganic anion and a buffer at pH of 5.5 to 7.0, and the liquid composition is stable at room temperature for at least 6 months; and the specification indicates an antioxidant such as methionine may usually be added to the composition (paragraph [0044]). Since both the claims of the instant application and the claims of the copending application are directed to a pharmaceutical composition comprising an EPO glycoprotein product such as pegylated EPO product, a multiple charged inorganic anion, a buffer at pH of 5.5 to 7.0 and methionine. Thus, claims 1-16, 18, 22-37 and 39-68 in present application and claims 23-35, 38-42, 51-55, 59-61 and 67-77 in the copending application are obvious variations of a

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pharmaceutical composition comprising a pegylated EPO glycoprotein product having the in vivo biological activity, a multiple charged inorganic anion, a buffer at pH of 5.5 to 7.0 and methionine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response, applicants request this provisional rejection be held in abeyance until there is indication of allowable subject matter in either application. The response has been fully considered. However, the argument is not found persuasive because as long as the rejection maintains, the allowable subject matter cannot be indicated.

Conclusion

13. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

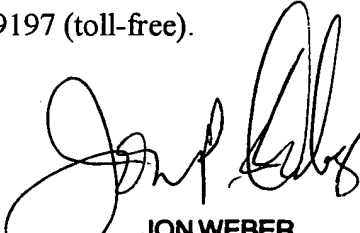
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner


JON WEBER
SUPERVISORY PATENT EXAMINER

CMK
May 28, 2005